K023280

(1)

SMDA 510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807 subpart E, Section 807.92.

DEC 19 2002

A. Sponsor /Manufacturer Name and Address

1. Applicant
   Olympus Optical Co., Ltd.
   2-3-1 Shinjuku Monolis Nishi-shinjuku
   Shinjuku-ku, Tokyo, Japan, 163-0914
   Establishment registration number : 8010047
2. Initial Importer
   Olympus America Inc.
   Two Corporate Center Drive
   Melville, NY 11747-3157
   Establishment registration number : 2429304
3. Contact Person
   Laura Storms-Tyler
   Director, Regulatory Affairs
   Olympus America Inc.
   Two Corporate Center Drive
   Melville, NY 11747-3157
   Tel 631-844-5688
   Fax 631-844-5416

B. Device Name, Common Name

1. Common/Usual Name
   Electrosurgical Unit and its ancillary equipment.
2. Device Name
   Olympus PSD-20 Electrosurgical System and its associated accessories
3. Classification
   21 CFR 876.4300 Endoscopic electrosurgical unit and accessories, Class II

C. Identification of the predicate or legally marketed device

The following devices are substantially equivalent device in consideration to its characteristics or specification.

Model Name	510(k)	Applicant
Olympus PSD-20 Electrosurgical Unit and its associated accessories (For GI application)	K970797	Olympus Optical Co., Ltd.
Olympus UES-20 Electrosurgical Units and its associated accessories (For urology application)	K970184	Olympus Optical Co., Ltd.

D. Device Description

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(2)

1. Summary

This instrument has been designed to be used with Olympus recommended Electrosurgical accessories, Endoscope, Light Source and other ancillary equipment for flexible cystoscopic treatment (cutting and coagulating)

Recommended endoscopes for this instrument are Olympus's series CYF series, and Olympus's electrosurgical instruments such as electrosurgical snare, hot biopsy forceps. Other Olympus electrosurgical devices or instruments can be used with this subject device. Be sure to check compatibility for each device in each instruments instruction manual. The PSD-20 unit offers Monopolar, output modes; 5 Cut modes (PURE, BLEND 1/2/3/4), 1 Coagulation mode, (NORMAL COAGULATION), It offers several features to ensure the safe operation of the unit. For example, the voltage output level setting and a monitor circuit detect irregularity or improper connections.

2. Design

This device has been designed to be complying with the following voluntary standards.

- IEC 60601-1
- IEC 60601-2-2
- IEC 60601-2-18
- IEC 60601-1-2 (EMC)

3. Materials

There aren't any patient contacting material in PSD-20 itself. Some ancillary equipment have patient contact materials, however there are no new patient contacting material in those devices.

4. Technology

This device does not have any special technology or characteristic i.e. this device is intended to provide electrical power to accessories (such as biopsy) via the use of high frequency electrical current waveform passing into the tissue during endoscopic urological treatment.

E. Indication for Use

This instrument has been designed to be used with Olympus recommended Electrosurgical accessories, Endoscope, Light Source and other ancillary equipment for flexible cystoscopic treatment (cutting and coagulating) including:

- Hemostasis of superficial bleeding
- Treatment of bladder tumors
- Treatment of stenosis inside urinary tract.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olympus Optical Company, LTD.
Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America Inc.
Two Corporate Center Drive
Melville, New York 11747-3157

DEC 19 2002

Re: K023280
Trade/Device Name: Olympus PSD-20 Electrosurgical System
Regulation Number: 878.4400
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 30, 2002
Received: October 1, 2002

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number(if known): K023280

Device Name: Olympus PSD-20 Electrosurgical System and its associated accessories

Indications for Use:

This instrument has been designed to be used with Olympus recommended Electrosurgical accessories, Endoscope, Light Source and other ancillary equipment for flexible cystoscopic treatment (cutting and coagulating) including:

- Hemostasis of superficial bleeding
- Treatment of bladder tumors
- Treatment of stenosis inside urinary tract.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

Division of General, Restorative
and Neurological Devices

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